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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/522,148      | 01/24/2005  | Mate Hidvegi         | 3494-0104PUS1       | 9131             |

2292 7590 09/07/2006

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| EXAMINER |
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DAVIS, DEBORAH A

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| ART UNIT | PAPER NUMBER |
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1655

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/522,148

**Applicant(s)**

HIDVEGI ET AL.

**Examiner**

Deborah A. Davis

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 24 January 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered ***with the exception of those documents cited by the examiner on form PTO 892.***

### ***Claim Objections***

2. Claim 15 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and not and cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 15 has not been further treated on the merits.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 8-15 provides for the use of a fermented wheat germ extract and an anti-inflammatory agent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to

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encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1 and 8-15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5. Claim 15 recites the limitation "the usual fodder" in lines 2 through 3. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 9-11 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a treatment of Mycoplasma infections and coccidiosis infections in poultry using an effective amount of fermented wheat germ extract, does not reasonably provide enablement for a prevention of the above conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant has reasonably

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demonstrated/disclosed that the claimed fermented wheat germ extract is a useful therapeutic agent in treating the above conditions. However, the claims also encompass using the claimed extract to prevent the above named conditions which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) – including preventing such conditions as Mycoplasma infections and other infectious inflammations (which clearly are not recognized in the medical art as being a totally preventable condition).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hidvegi et al (WO 99/08694).

A fermented wheat germ extract is apparently claimed,

The cited reference teaches a fermented wheat germ extract obtained by fermenting wheat germ with *Saccharomyces cerevisiae* as claimed (see entire document). Therefore, the reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hidvegi et al (WO 99/08694).

Hidvegi et al. teach a fermented wheat germ extract obtained by fermenting wheat germ with *Saccharomyces cerevisiae*, including in a form known as a "dried vegetal material" and that the dried vegetal material can be within the food industry - e.g., a dietary supplement (see, e.g., page 5, line. 29 - page 6, line 4). Hidvegi et al. do not expressly teach adding the fermented wheat germ extract to fodder (to enhance weight gain), as instantly claimed.

However, the cited reference beneficially teaches that the fermented wheat germ extract is therapeutically useful as an immunostimulatory agent when administered to animals (see entire document including Abstract, Examples, Claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add a therapeutically effective amount of the wheat

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germ extract taught by Hidvegi et al. to fodder (animal feed) so as to provide the immunostimulatory effect to farm animals based upon the beneficial teachings provided by the cited reference. The adjustment of particular conventional working conditions (e.g., determining an effective amount of fermented wheat germ extract therein) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan. Please note that giving a farm animal the dried vegetal material (i.e., fermented wheat germ extract) within a food such as fodder would intrinsically enhance weight gain therein (as instantly claimed).

Thus, the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

With respect to the art rejections above, it is noted that the cited reference does not teach that the composition can be used in the various manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case (based upon the claims, as drafted – i.e., “Use of “ claims), the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and under 103 (MPEP 2112).

***Conclusion***

12. No claims are allowed.
13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McKelvey Terry can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

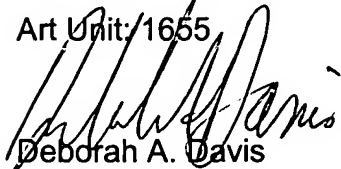
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Deborah A. Davis

Patent Examiner

August 2006



CHRISTOPHER R. TATE  
PRIMARY EXAMINER